

Orbital Atherectomy for FP Lesions: Advantage and Limitations



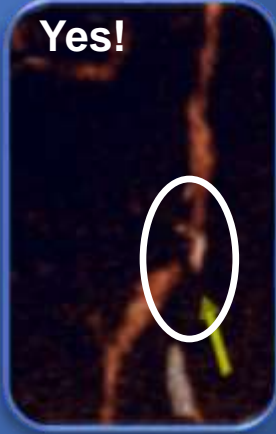
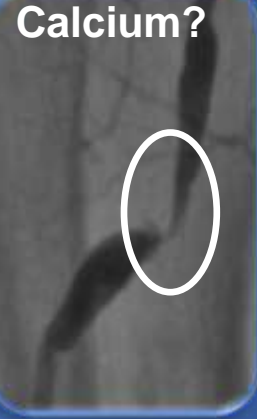
David Geffen
School of Medicine



Michael S. Lee, MD, FACC, FSCAI
Interventional Cardiology

SEVERELY CALCIFIED LESIONS

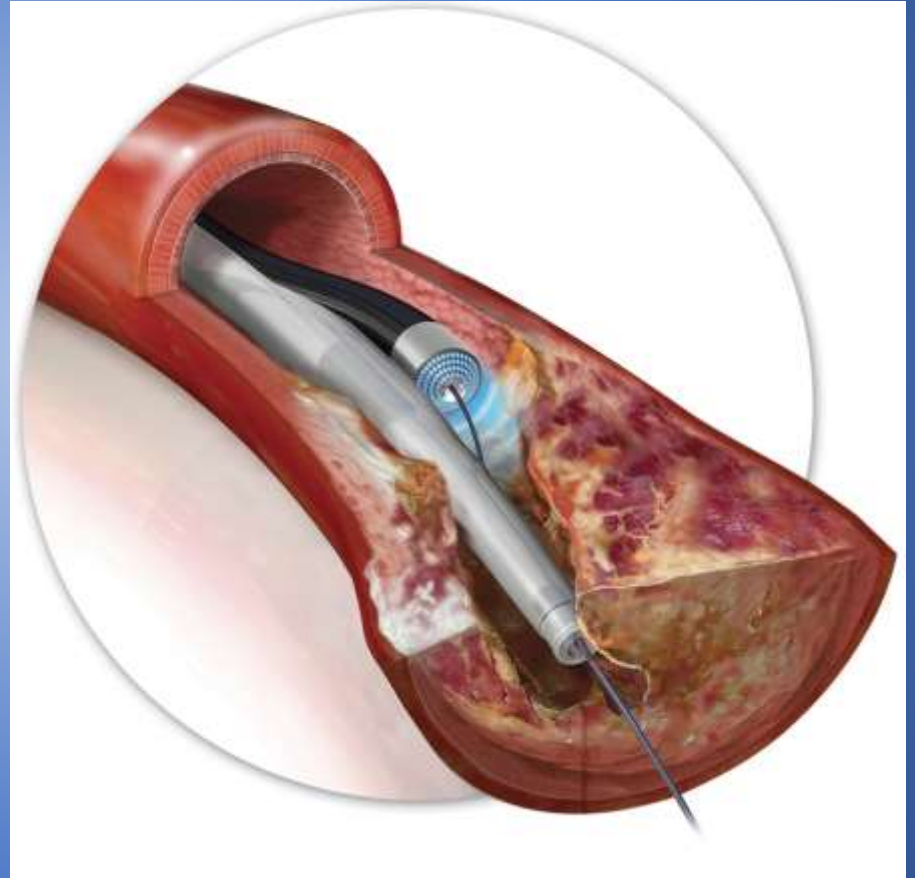
- Angiography underestimates severity of calcification^{1,2}
- Technically challenging³⁻⁶
 - Respond poorly to angioplasty
 - Vessel recoil after balloon dilatation
 - Flow-limiting dissection related to high inflation pressure
 - Make stent placement difficult
 - Suboptimal stent expansion
- Higher procedural complication rates^{3,6,7}



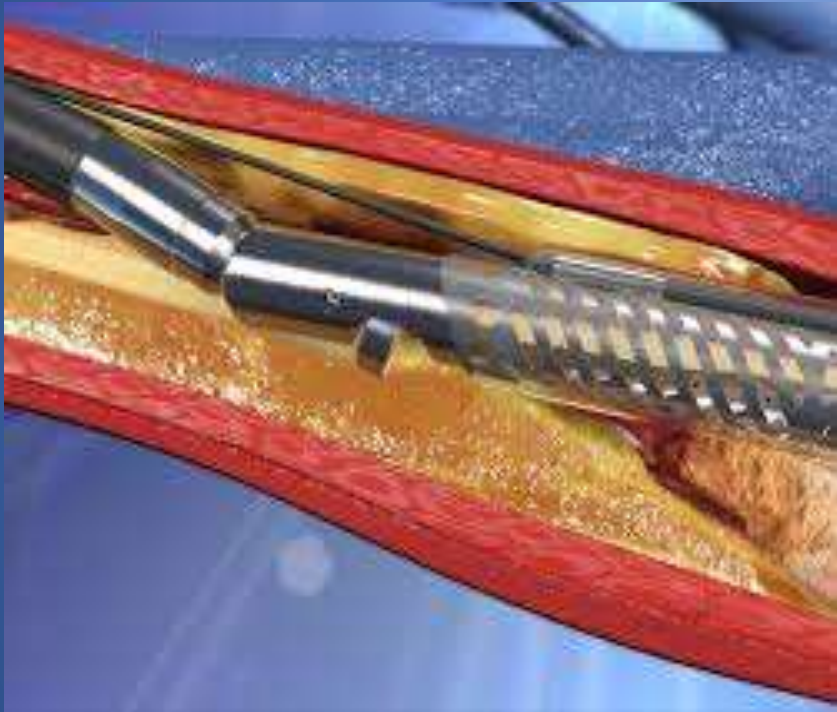
1. Kashyap VS, et al. *J Endovasc Ther.* 2008;15:117-125.
2. Van Lankeren W, et al. *Cardiovasc Intervent Radiol.* 1998;21:367-374.
3. Fitzgerald PJ, et al. *Circulation.* 1992;86:64-70.
4. Henry M, et al. *Tex Heart Inst J.* 2000;27:119-126.
5. Rogers JH and Laird JR. *Circulation.* 2007;116:2072-2085.
6. Cioppa A, et al. *Cardiovasc Revasc Med.* 2012;13:219-223.
7. Mustapha J, et al. *Vasc Dis Manag.* 2013;10:E198-207.

Laser Atherectomy

Ineffective against severe calcification



Directional Atherectomy



- May not cross severely stenotic calcified lesions
- Unidirectional ablation

Jetstream Device



Requires 7F sheath

Diamondback 360[®] Peripheral Orbital Atherectomy Systems

Sleek Electric-Powered Handle

- Simple device set-up
- Optimum torque transfer to the shaft and crown
- Equipped with GlideAssist[®] Mode (Available on all Exchangeable SKUs and the Diamondback 1.25 Micro)

Crowns

Micro



Solid

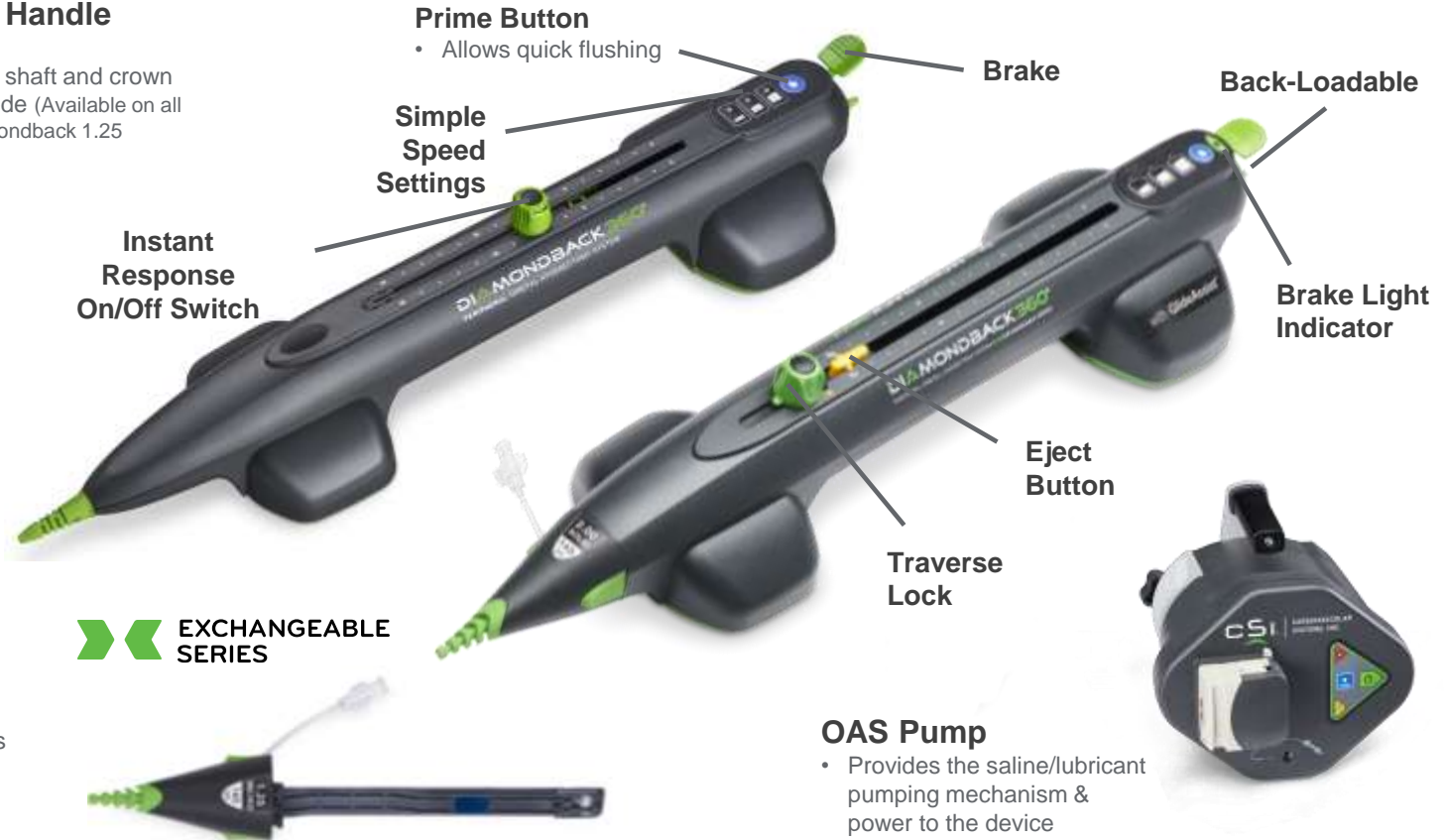


Classic



Exchangeable Series Features

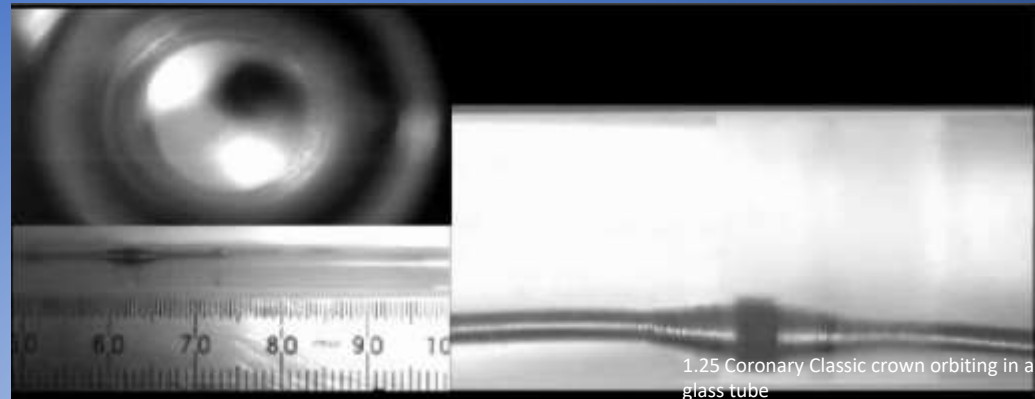
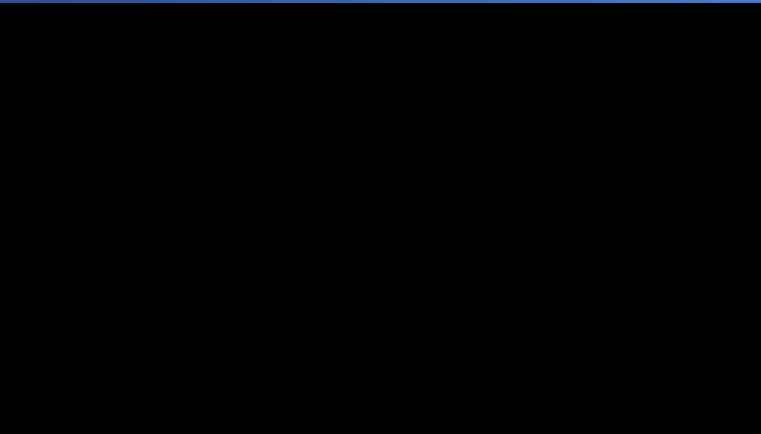
- Interchangeable cartridge sizes
- Improved tactile feel



OAS Pump

- Provides the saline/lubricant pumping mechanism & power to the device
- Mounts directly to an IV pole

Orbital Atherectomy Mechanism of Action



Differential Sanding:

- 30 micron diamond coating
- Bi-directional sanding, eccentric mounted crown
- Healthy elastic tissue flexes away minimizing damage to the vessel

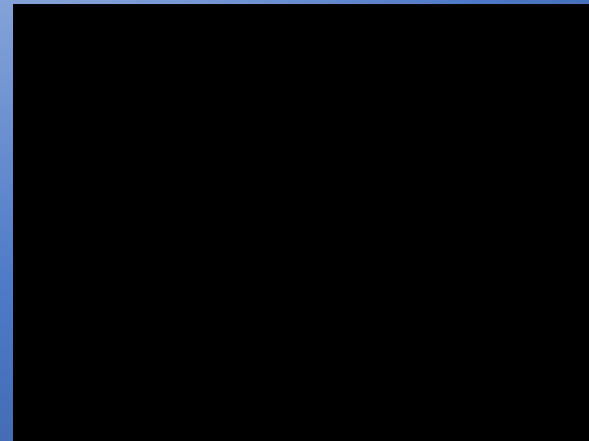
Centrifugal Force:

- 360° crown contact designed to create a smooth, concentric lumen
- Allows constant blood flow and particulate flushing during orbit
- Increasing speed = increases radius of orbit
- Ability to treat multiple vessel diameters with one crown
- Treat large vessels through small sheaths

Micro-particulate



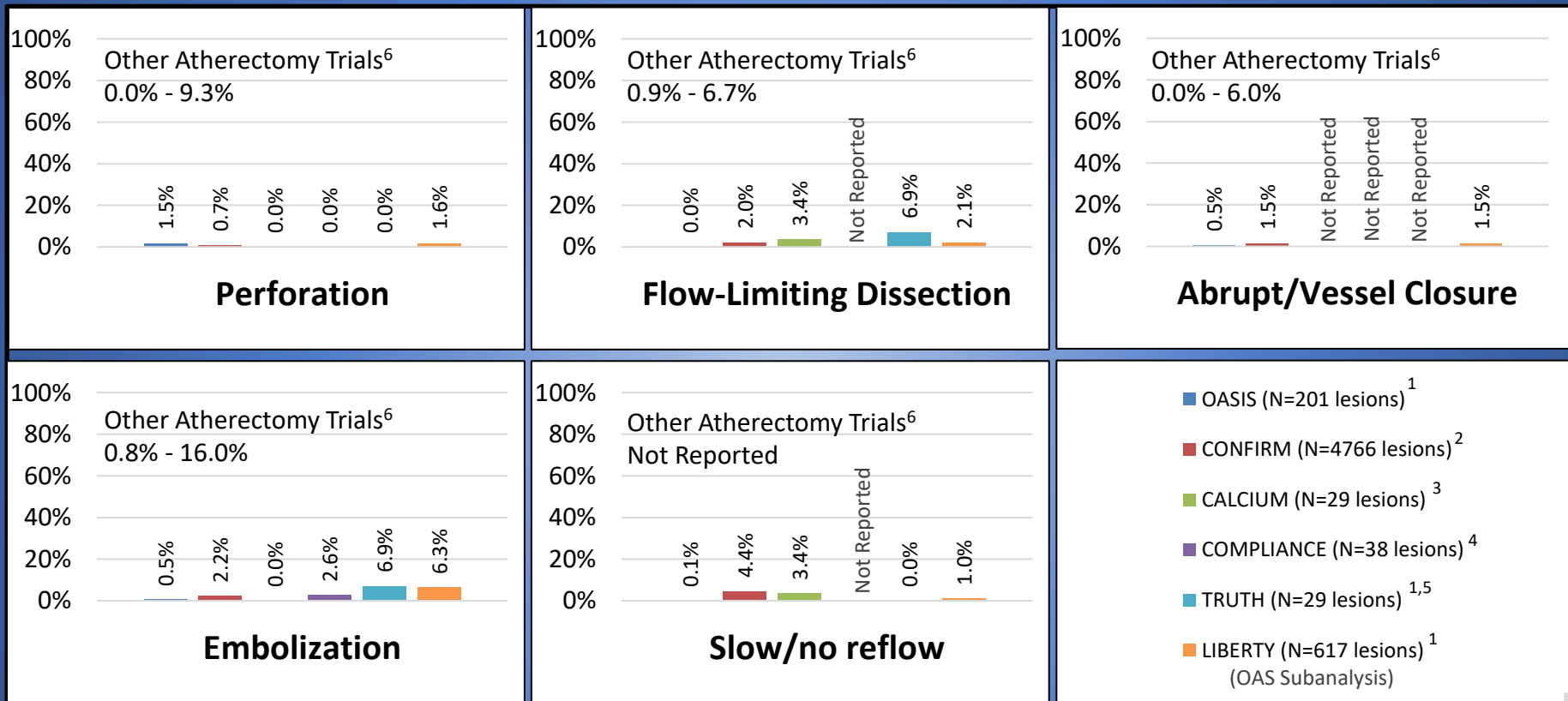
Crown will only sand the hard components of plaque



Soft components (plaque/tissue) flex away from crown

Excellent Procedural Safety Profile

Consistently Low Acute Complication Rates



Excellent safety profile demonstrated by low angiographic complication rates.

1. CSI data on file.

2. Das T, et al. Catheter Cardiovasc Interv. 2014;83:115-22. (Flow-limiting dissections and embolization were not tracked in 1146 lesions)

3. Shammas NW, et al. J Endovasc Ther. 2012;19:480-488.

4. Dattilo R, et al. J Invasive Cardiol. 2014;26:355-60.

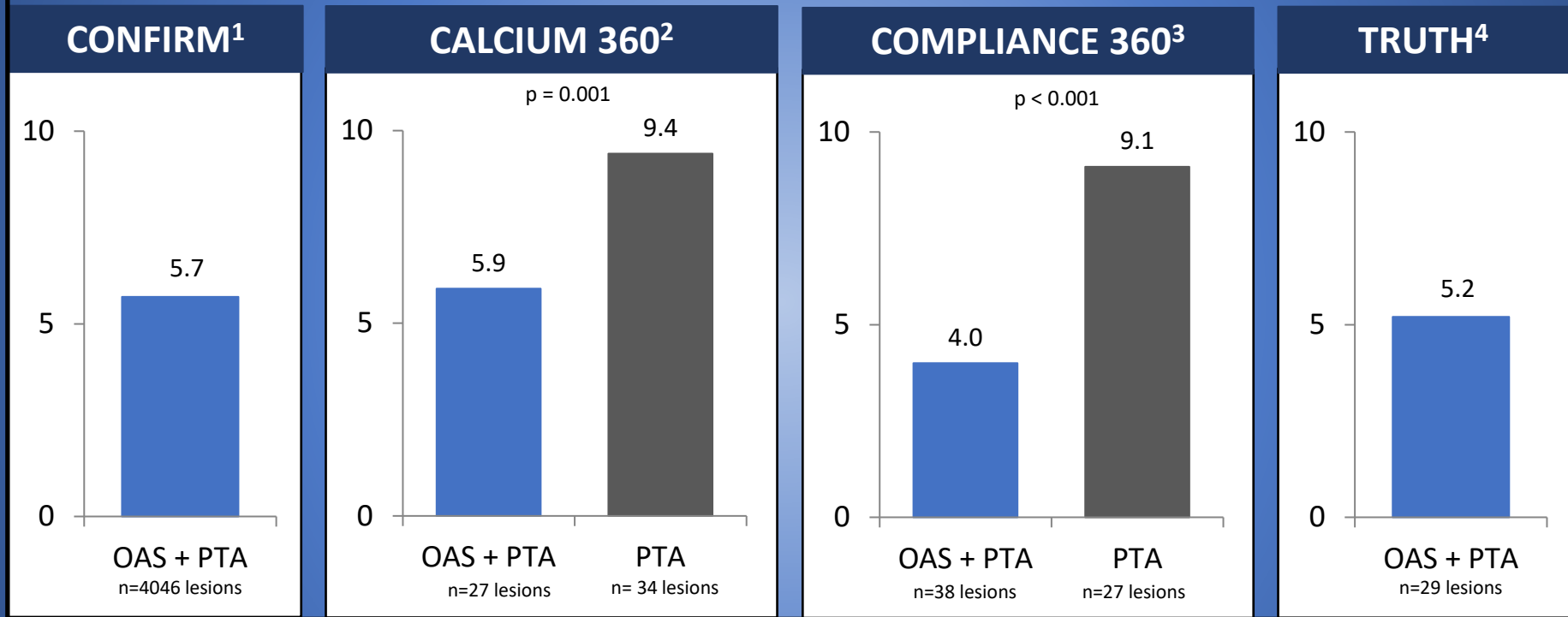
5. Babaev A, et al. Vasc Endovascular Surg. 2015;49:188-94.

6. Martinsen B, Evaluation and Use of Atherectomy Devices for CLI in US, Japan, and EU: Industry View VIVA 2017. (Includes directional, rotational, laser)

Lesion Modification

Allows for Low Balloon Inflation Pressures

Mean Max Balloon Inflation Pressure (atm)

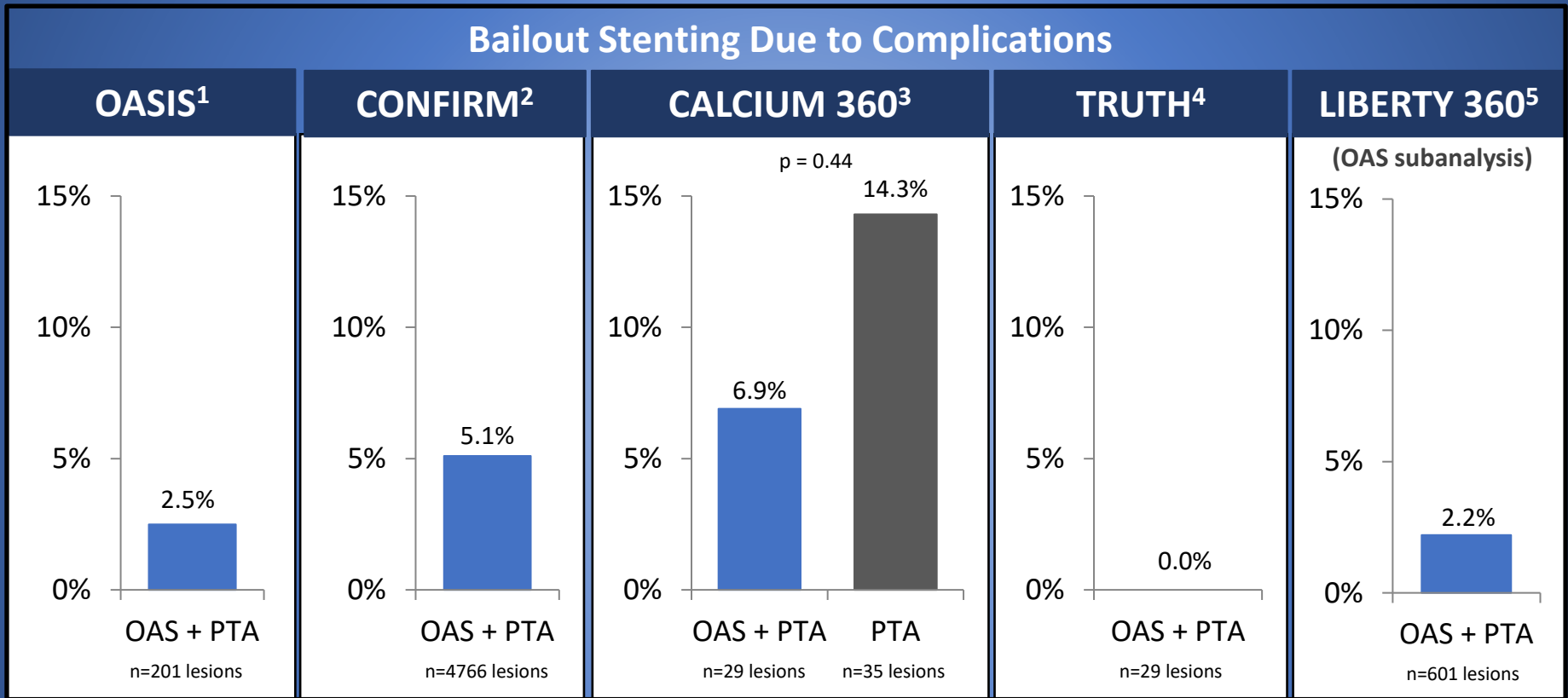


Successful lesion modification results in **low pressure balloon inflation.**

1. Das T, et al. Catheter Cardiovasc Interv. 2014;83:115-22
2. Shammas NW, et al. J Endovasc Ther. 2012;19:480-488.
3. Dattilo R, et al. J Invasive Cardiol. 2014;26:355-60.
4. Babaev A, et al. Vasc Endovascular Surg. 2015;49:188-94.

Minimizes Vessel Damage

Decreased Need for Bailout Stenting



Minimized vessel damage reduces need for bailout stenting.

1. CSI Data on file (any adjunctive stenting)

2. Das T, et al. Catheter Cardiovasc Interv. 2014;83:115-22. (Stenting due to dissection)

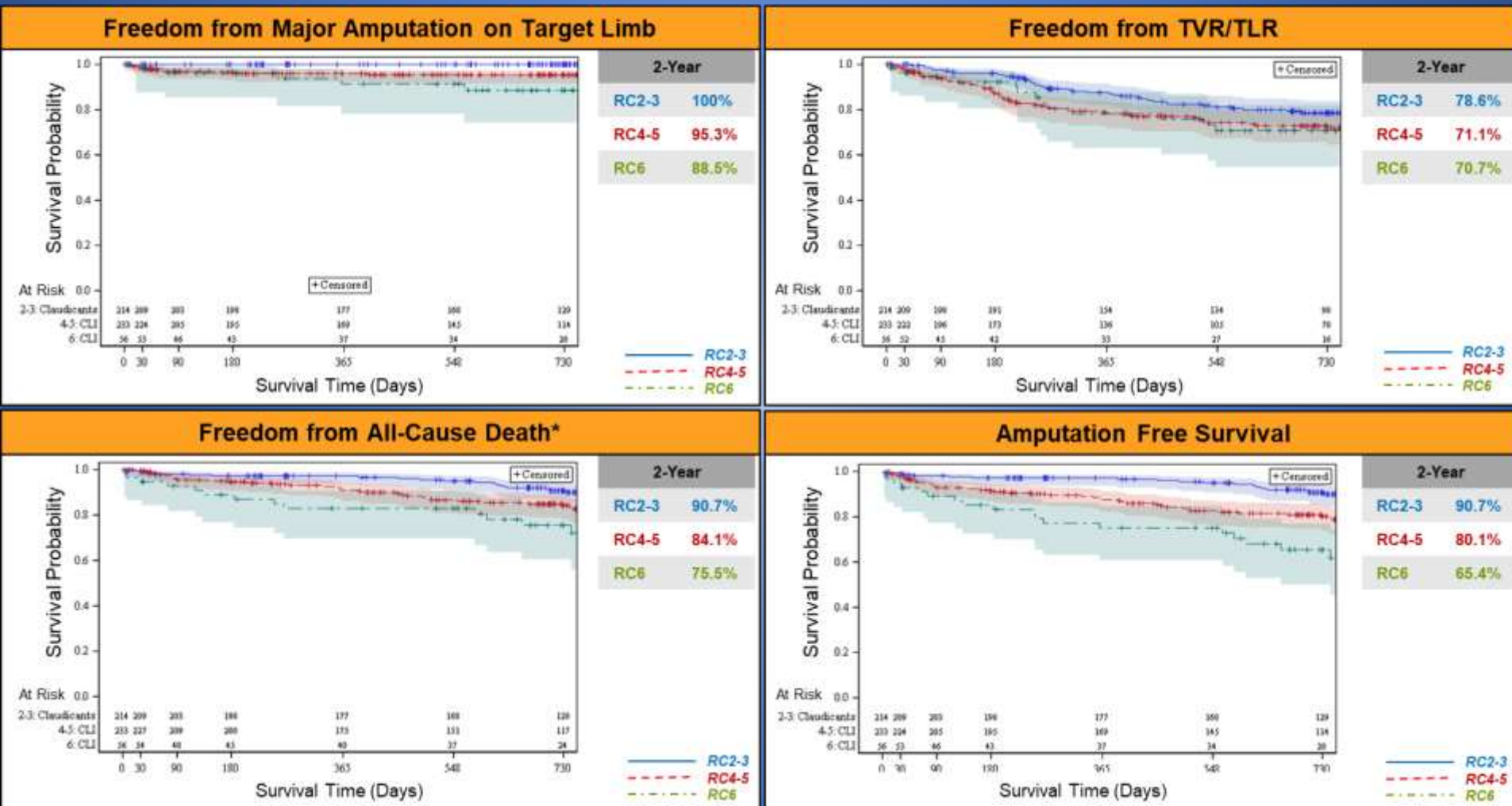
3. Shamas NW, et al. J Endovasc Ther. 2012;19:480-488. (Stenting for >30% residual stenosis, type C-F dissection, or significant recoil)

4. Babaev A, et al. Vasc Endovascular Surg. 2015;49:188-94. (Stenting due to dissection)

5. CSI Data on file (15-Jun-2018 data, any unplanned stenting not attributed to physician preference)

LIBERTY Orbital Atherectomy (OAS) Subanalysis: Outcomes through 2 Years

OAS was the most frequently used atherectomy device. High freedom from major amputation in all Rutherford Classes (RC2-3, 100%; RC4-5, 95.3%; and RC6, 88.5%). Similar rates of freedom from TVR/TLR were seen across all Rutherford Classes.



Kaplan-Meier method used to obtain estimate rates. Greenwood's method used to obtain the 95% confidence interval for the estimate.

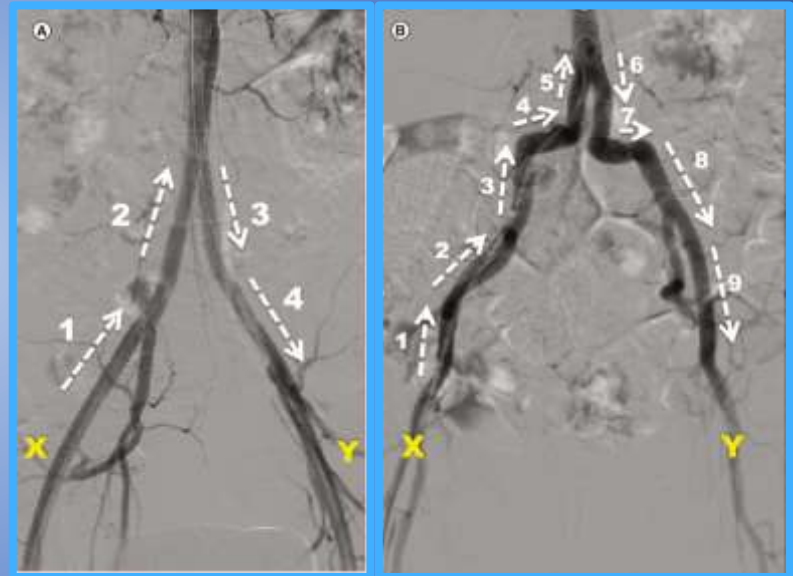
*All-Cause Death rate shown here is at 2 years, but the Freedom from MAE only includes death within 30-days of the procedure

Mustapha J. Late Breaking: LIBERTY 360° Trial 2-Year Update. Presented at AMP; August 8, 2018; Chicago, IL.

WHY RADIAL?

Many factors can complicate femoral access¹

- Bilateral hostile groins, including history of bilateral femoral surgery and/or obesity
- Bilateral infrainguinal lesions
- Presence of kissing iliac stents or bifurcated aortic grafts



Arrows represent the vectors into which a force applied at point "X" would decompose before reaching point "Y" in normal (Image A) vs. diseased (Image B) anatomies.²

1. Coscas R, et al. J Vasc Surg. 2015;61(2):463-468.
2. Mustapha JA, et al. Interv Cardiol. 2015;7(5):451-468

WHY RADIAL?

Utilization of the radial artery for peripheral procedures provides several unique benefits compared to femoral access:

- Reduces access site complications¹
- Avoids difficult sheath placement¹
- Allows immediate ambulation and shorter discharge time¹
- Eliminates need of compression of the femoral artery (femoral closure devices)¹
- Improves patient experience^{1,2}

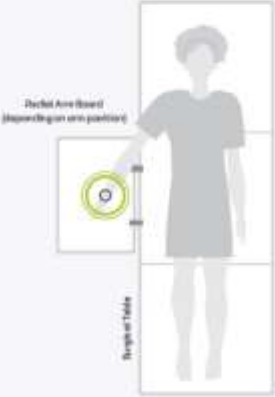


1. Sanghvi K, Coppola J. *Intervent Cardiol Clin.* 2015;4(2):179–192.

2. Thakor A, et al. *Can Assoc of Radiol J.* 2017;68(3):318-327.

RADIAL ACCESS SITE OPTIONS

- Driven by physician and staff preference
- Cath lab room size
- Patient height and lesion location

RADIAL PROCEDURE ROOM SET UP OPTIONS**

RIGHT SIDE ACCESS SITE	LEFT SIDE ACCESS SITE	RIGHT SIDE ACCESS WITH LEFT ARM CROSS OVER
 <p>PROS</p> <ul style="list-style-type: none"> - Greater operator comfort and staff familiarity with set up - Similar room set up to femoral PVI cases - Enables operator to position radiation shield to reduce exposure - Simple/accessible vascular pathway to aorta <p>CONS</p> <ul style="list-style-type: none"> - Increases working length distance needed for devices vs. left side access length 	 <p>PROS</p> <ul style="list-style-type: none"> - Reduces device lengths needed and maximizes the working length of devices - Enables operator to position radiation shield to reduce exposure <p>CONS</p> <ul style="list-style-type: none"> - Room set up may need to be modified - Small room size can be an issue when working with longer length devices 	 <p>PROS</p> <ul style="list-style-type: none"> - Greater operator comfort and staff familiarity with set up <p>CONS</p> <ul style="list-style-type: none"> - Potential for increased radiation exposure - Left hand may block imaging view when accessing the right SFA (superficial femoral artery)

**All information based on Dr. Arun Lodha's experience

EXTENDED LENGTH PERIPHERAL ORBITAL ATHERECTOMY

Simple

Same user-friendly orbital atherectomy platforms -
Diamondback 360[®], Stealth 360[®], and Diamondback
360[®] Exchangeable Series

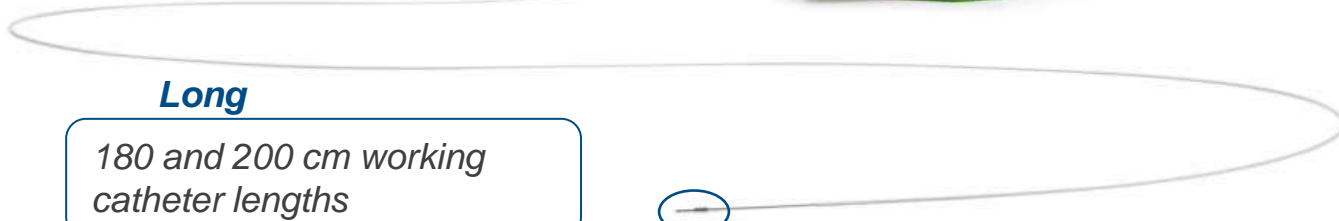
Low-Profile

5 Fr compatible sheath for
ALL extended length devices



Long

180 and 200 cm working
catheter lengths



Supportive

Nylon sheath with lubricious additive
and increased filar count on driveshaft



CSI'S EXTENDED LENGTH OAS PORTFOLIO

CSI's Orbital Atherectomy System

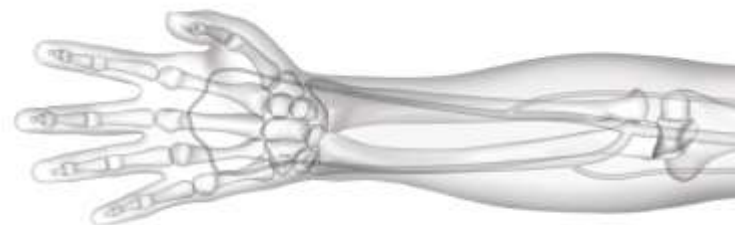
- The only atherectomy system allowing you to treat via the radial artery
- Available in 180 and 200 cm working catheter lengths
- Offered in the Diamondback 360® and Diamondback 360 Exchangeable Series

ViperCath™ XC Peripheral Exchange Catheter

- Longest length exchange catheter available
- Comes in a 200 cm length
- 5 Fr crossing profile

ViperWire Advance® Guide Wires

- Available in 475 cm length
- 0.014"/0.014" and 0.014"/0.018" tip configurations



**EXTEND YOUR
OPTIONS.**
THE RADIAL ACCESS ALTERNATIVE.

REACH PVI STUDY



Purpose: To prospectively evaluate acute clinical outcomes of orbital atherectomy (OA) via transradial access for treatment of PAD in lower extremity lesions

- Prospective, observational, single-arm, multi-center (6 sites in the U.S.), post-market
- 50 subjects enrolled

Primary
Outcome

Procedural Success: Successful completion of OA treatment of target lesion via transradial access without serious transradial access related events

Secondary
Outcome

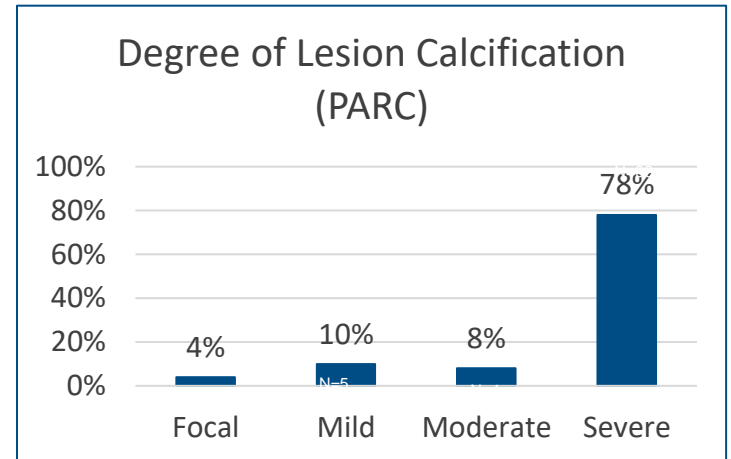
Treatment Success: Final residual stenosis <50% without stent placement or <30% residual stenosis with stent placement and without significant angiographic complications

Target Lesion Characteristics

Most common target lesion location was SFA with high degree of severe calcification (78%).



N=50	
Lesion location	
Iliac	1 (2.0)
Common femoral artery	10 (20.0)
Superficial femoral artery	34 (68.0)
Popliteal artery	1 (2.0)
BTK	4 (8.0)
Lesion length (mm)	98.3 ± 87.5
Reference vessel diameter (mm)	6.1 ± 1.2
Pre-procedure diameter stenosis (%)	82.4 ± 9.8



Peripheral Academic Research Consortium (PARC) ¹	
Focal	<180° and less than one-half of the total lesion length
Mild	<180° and greater than one-half of the total lesion length
Moderate	≥ 180° and less than one-half of the total lesion length
Severe	≥ 180° and greater than one-half of the total lesion length

1. Patel M, et al. J Am Coll Cardiol. 2015; 65(9):931-41. Physician-reported data; continuous variables presented as mean ± SD; categorical variables presented as n (%). Lodha A. REACH PVI Clinical Study Results. Presented at NCVH 2020.

Access Sites for Target Lesion Treatment

Majority of target lesions were accessed via left radial artery (78%) and radial hemostasis compression device was most frequent closure method (88%); minimal utilization of non-radial access site.



Radial Access	N=50
Access side	
Right	11 (22.0)
Left	39 (78.0)
Maximum diameter of guide catheter*	
4 Fr	1 (2.0)
5 Fr	7 (14.0)
6 Fr	41 (82.0)
7 Fr	1 (2.0)
Radial hemostasis compression device [#]	44 (88.0)
Time to hemostasis (min)	104.7 ± 89.2

Non-Radial Access	N=3
Pedal access	N=2
Tibial access	N=1
Primary reason for access	
Could not access lesion due to complex anatomy	1 (33.3)
Treat complication	2 (66.7)

* Although extended length OAD is 5 Fr compatible, other devices (e.g., balloon, stent) with varying Fr compatibility may have been used during the target lesion treatment.

[#] Data on manual or direct pressure closure method on 6 subjects is under review.

Continuous variables presented as mean ± SD; categorical variables presented as n (%).

Lodha A. REACH PVI Clinical Study Results. Presented at NCVH 2020.

Target Lesion Treatment

Low final residual stenosis (7.6%).



Target Lesion Treatment	N=50
Pre-OAD balloon treatment	0 (0)
Orbital atherectomy treatment	50 (100.0)
Number of OA devices*	1.0 ± 0.0
Post-OAD balloon treatment	49 (98.0)
Balloon nominal pressure (atm)	8.0 ± 1.0 (N=49)
Maximum inflation pressure (atm)	8.9 ± 2.4 (N=48)
Stent placement	8 (16.0)
Reason for stent use	N=8
Angiographic complication	1 (12.5)
Physician preference/pre-planned	6 (75.0)
Sub-optimal result (>50% stenosis)	1 (12.5)
Final residual stenosis (%)	7.6 ± 9.2

* 48/50 OA devices were extended length models (180 cm or 200 cm shaft)
Physician-reported data; continuous variables presented as mean ± SD;
categorical variables presented as n (%).

Lodha A. REACH PVI Clinical Study Results. Presented at NCVH 2020.

Primary Outcome: Procedural Success

High procedural success (98%) with no reported serious transradial access related events.



	N=50
Procedural success (target lesion)	49 (98.0)
Successful completion of OA treatment	50 (100.0)
OA treatment completed via transradial access	49 (98.0)
Serious transradial access related events	0 (0.0)
Serious TRA site bleeding (BARC Type 2-5)	0 (0.0)
Serious TRA site hematoma	0 (0.0)
Serious radial artery spasm	0 (0.0)
Serious hand ischemia	0 (0.0)
Serious nerve damage	0 (0.0)
Serious TRA site pseudoaneurysm	0 (0.0)
Perforation	0 (0.0)
Stroke	0 (0.0)
Transient ischemic attack	0 (0.0)

Physician-reported data; categorical variables presented as n (%). Serious transradial access related events were reported from index procedure through first SOC follow-up within 7 - 45 days. Serious means the event met the criteria for serious adverse event a) led to a death, injury or permanent impairment to a body structure or a body function; b) led to a serious deterioration in health or the subject, that either resulted in: a life-threatening illness or injury, or a permanent impairment of a body structure or a body function, or in-patient hospitalization or prolongation of existing hospitalization, or medical or surgical intervention to prevent life threatening illness; c) led to foetal distress, foetal death or a congenital abnormality or birth defect.

Lodha A. REACH PVI Clinical Study Results. Presented at NCVH 2020.

Secondary Outcome: Treatment Success

High treatment success (98%) and low significant angiographic complication rate (2%).



	N=50
Treatment success (target lesion)	49 (98.0)
Final residual stenosis <50% without stent placement or <30% with stent placement	49 (98.0)
Significant angiographic complications	1 (2.0)
Dissection (Type D-F)	1 (2.0)
Perforation	0 (0.0)
Serious slow flow/no reflow	0 (0.0)
Serious acute vessel closure	0 (0.0)
Serious distal embolization	0 (0.0)
Serious thrombus formation	0 (0.0)

Physician-reported data; categorical variables presented as n (%). Significant angiographic events were reported from index procedure through first standard of care follow-up within 7 - 45 days.

Lodha A. REACH PVI Clinical Study Results. Presented at NCVH 2020.

Overall Procedure

Short time to ambulation (2.7hrs) and Length of Stay (LOS) (7.2hrs)—key economic benefits of radial access.



Procedural Parameters*	N=50
Procedure time (min)	46.9 ± 18.2
Fluoroscopy time (min)	19.1 ± 8.0
Contrast volume (mL)	114.1 ± 107.5
Time to ambulation (hours)	2.7 ± 1.3
LOS (hours): Time from admission to discharge	7.2 ± 5.2

* Includes target and non-target lesions; average number of lesions treated: 1.9 ± 1.0
Procedure time defined as time from first guide catheter inserted to last guide catheter removed. Time to ambulation defined as time from last guide catheter removed to ambulation. Sites were trained to define time of ambulation as time of walking. Continuous variables presented as mean ± SD. LOS=length of stay
Lodha A. REACH PVI Clinical Study Results. Presented at NCVH 2020.

SUMMARY

- Transradial peripheral intervention reduces access site complications, and leads to earlier ambulation and shorter discharge time¹.
- The OAS is the only atherectomy system allowing for infrainguinal treatment via the radial artery with a high rate of procedural and treatment success.²

1. Sanghvi K, Coppola J. *Intervent Cardiol Clin*. 2015;4(2):179–192.
2. Lodha A. REACH PVI Clinical Study Results. Presented at NCVH 2020.



John Wooden

“Failing to prepare is preparing to fail.”

